UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,016	01/28/2002	Per Antonsson	003300-903	1277

21839 7590 04/07/2003

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
SALIMI, ALI REZA	

ART UNIT	PAPER NUMBER
1648	6

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/048,016	Antonsson et al
Examiner	**Art Unit**
A. R. SALMI	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 26, 2003* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above, claim(s) *2 and 6-28* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1 and 3-5* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *1 1/2*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group II (claims 1, 3, 4, and 5, and antigen comprising tumor as a specie in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the groups are drawn to sufficiently interrelated invention, applicants further assert the invention of II and III both consist of short peptides. This is not found persuasive because the cited evidence prove that the technical feature of Group I does not make a contribution over the prior art. Thus, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 as such the restriction is proper. In addition, the Groups II and III are indeed distinct as applicants admit on the record Group II is directed to T cells and Group III is directed to B cells activation, these are different inventions. Still further, "sufficiently" interrelated is not a legal ground not hold claims distinct and restrict-able.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 6-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected Groups. Applicants timely traversed the restriction (election) requirement in Paper No. 5. Claims 1, 3, 4, and 5 are considered within the elected specie of antigen comprising tumor.

Applicants are reminded to cancel the claims to the non elected claims.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Please note the claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and do not conform with current U.S. practice. The correction is respectfully requested.

Claim Rejections - 35 USC § 112

Claims 1, 3, 4, 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 4, 5 are vague and indefinite for recitation of "A carrier", the intended carrier is not defined, is this a buffer or perhaps a liposome? Please clarify. The claims have been interpreted in light of the specification and since the specification is extremely deficient in providing adequate teaching it is not clear what the said limitation intends to cover.

Still further, the term "intentionally modified" in claim 1 is a relative term, which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be

reasonably apprised of the scope of the invention. In the instant case, the said definition has many meanings, what applicants' regard as "modified" others might not and vis versa, and the specification does not provide clear teaching as to what is and is not considered to be "modified" protein. In addition, the claim is confusing for recitation of "a substance", what "substance" is this? Moreover, claim 1 is vague and indefinite for recitation of "type-specific epitope(s)" the intended metes and bounds of the epitopes are not defined. The claims have been interpreted in light of the specification and since the specification is extremely deficient in providing adequate teaching it is not clear what the said limitation intends to cover. This affects the dependent claims.

Claim 3 is vague and indefinite, the intended metes and bounds of "a peptide" is not defined. Is the peptide HPV L1 protein? This affects claims 4, 5.

Claim 4 is vague and indefinite, the intended T cell epitope is not defined. Is the epitope from a HPV?

The term "derived" in claim 5 is a relative term, which renders the claim indefinite. The term "derived" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably

apprised of the scope of the invention. The intended "antigen comprising tumor" is not defined. Is the antigen form a papillomavirus tumor?

Claim Rejections - 35 USC § 112

Claims 1, 3, 4, 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is extremely deficient in providing adequate teaching for the claimed invention. Applicants are reminded that this field is considered to be highly unpredictable, as applicants own statement throughout the disclosure is testament to the unpredictability of the field, and absent adequate teaching one of ordinary skill in the art would be required to conduct large quantity of undue experimentation to enable the claimed invention. There are no teaching in the specification about which"epitopes" or regions are ~~are~~ removed, either "intentionally" or otherwise, to modify the L1 so it won't induce antibodies. There is no teaching as to what peptides or epitopes or T cell epitopes of tumor antigen is being fused to the so called modified L1 protein. The claimed invention and the specification is extremely confusing, in one breadth the claims read on inducing immune response while avoiding immune response against the very same tumor. In other scenario the claimed product is supposedly capable of inducing immune response against multiple papillomaviruses due to cross reactivity of shared regions. But how can one know which region to delete or maintain to obtain such cross reactivity? It even appears applicants are directing the invention or alluding to the fact that their invention is a gene therapy

"carrier", but no construct has been taught, no expression of any gene, even a marker gene, has been disclosed. In addition, what "substance" is being introduced into cells? Where is teaching for introduction of any gene or any antigen or any epitope into cells? No data has been shared with the Office, so no independent opinion can be rendered. The disclosure provides no examples, applicants are expecting others to enable their invention while they are obtaining patent protection, but this cannot be especially in an unpredictable field. Absent teaching by the applicant one ordinary skilled in the art would be required to conduct large quantity of undue experimentations to enable the claims, see In re Vaeck, 20 USPQ2d 1438 (CA FC 1991, at page 1445) wherein the board has indicated that "there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation." The applicant can not rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).*

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant disclosure, the applicants have not disclosed the structure of product reasonably enough which would convey they were in possession of what they consider to be their claimed invention. The specification does not set forth the metes and bounds of that encompasses modified peptides, or fusion peptides of any kind, or a "carrier", and there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed regions where the region may encompass. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art ... to make and

use" the invention. Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged

conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloch et al (WO 97/46693).

The claims and teaching of the above cited reference anticipates the claimed invention. The above cited reference taught a non-infectious virus-like particle (VLP) wherein ~~the~~ a region of the L1 is substituted for a second protein (see the abstract, and the claims).

Claims 1, 3, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Gissmann et al (WO 96/11272).

The claims and teaching of the above cited reference anticipates the claimed invention. The above cited reference taught a structural protein of L1 wherein several sections have been deleted and still form virus like particles (VLPs) and which further were fused to a second peptide such as L2 (see the abstract, and the claims). The deleted L1 meets the "modified" limitation and the fusion of L2 to L1 meets the "second peptide" limitations as well as the antigen comprising tumor and/or T cell epitope. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, 4, 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Burger et al (WO 99/48518).

The claims and teaching of the above cited reference anticipates the claimed invention. The above reference taught a composition comprising a fusion protein that does not contain any papillomavirus non-specific epitopes and auxiliary agents and at least

fusion protein is L1 and E protein of papilloma virus (see the abstract). The deleted L1 meets the "modified" limitation and the fusion of E protein fusion to L1 meets the "second peptide" limitations as well as the antigen comprising tumor and/or T cell epitope. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Gissmann et al (U.S. Patent No. 6,066,324).

The claimed invention is anticipated by the product disclosed in any one of claims 1-8 of above cited patent. The above cited patent taught a modified L1 protein. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, 4, 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Bloch et al (U.S. Patent No. 6,420,160 B1).

The claims and teaching of the above cited reference anticipates the claimed invention. The above cited reference taught a non-infectious virus-like particle (VLP) wherein the a region of the L1 is substituted for a second protein (see the abstract, and the claims). The non-infections L1 meets the "modified" limitation and the chimeric of L1 to E7 of claim 2 of the cite patent meets the "second peptide" limitations as well as the antigen comprising tumor and/or T cell epitope. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Gissmann et al (U.S. Patent No. 6,361,778 B1).

The claimed invention is anticipated by the product disclosed in any one of claims 1-5 of above cited patent. The above cited patent taught a modified L1 protein. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Gissmann et al (U.S. Patent No. 6,066,324).

The claimed invention is anticipated by the product disclosed in any one of claims 1-8 of above cited patent. The above cited patent taught a modified L1 protein. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See

In re Casey, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

4/7/2003

ALI R. SALIMI
PRIMARY EXAMINER